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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY. DOCKET NO.	CONFIRMATION NO.
09/960,477	09/24/2001	Yuji Ishihara	2001-1276	6807

513 7590 12/30/2005

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EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/960,477	ISHIHARA ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-17 and 19-35* is/are pending in the application.

4a) Of the above claim(s) *14-16,19,21-25 and 31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-13,17,20,26-30 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-8-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Applicant's amendment of 10-14-05 has been fully considered.

Claims 1, 5-17 and 19-35 are pending.

Claims 14-16, 19, 21-25 and 31-34 are withdrawn.

Claims 1, 5-13, 17, 20, 26-30 and 35 remain for consideration.

Applicant's argument has been considered, but not found persuasive. Thus, the previous rejections of 112/1st paragraph and 103 are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 5-13, 20, 26-30 and 35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over **Goto et. al.** (US 5,527,800) and further in view of the teachings of Tobin et. al. and Lai et. al. The rejection is maintained for the reasons stated in the previous action and for the following reasons:

   a. Applicant disputed that "the inhibition of AChE has the possibility of leading to action, which does <u>not</u> result in an improvement in urination function." Applicant

further explained that "inhibition of AChE may contract the bladder, not only on urination, but also during the urinary storage...It also impairs the normal urinary storage function of the bladder, which causes pollakiuria and incontinence of urine." Applicant concluded that "one of ordinary skill in the art would not reasonably expect that all of the AChE inhibitors disclosed in Gotto can function to improve urinary potency." (sic)

b. Applicant also cited the Hashimoto reference as "further evidence that one skilled in the art would not reasonably expect that a non-carbamate AChE inhibitor is most suitable for the treatment of dysuria (difficulty of urination) based on the teachings of Tobin et. al. and Lai et. al."

c. In response to applicant's argument, the following facts must be considered:

i. The instant method claims recite the **same compounds** disclosed by Goto et. al. (i.e., compounds # 38-40 in Table 63 on columns 207-208). It follows then, the compounds recited in the instant claims must have the **same AChE inhibitory** activity as those disclosed by Goto et. al.

ii. Although Goto et. al. had not used their compounds for improving excretory potency of a urinary bladder, it would have been **within the level of one skilled in the art** to determine the effect of Goto's compounds on urinary bladder based on the relationship between acetylcholine receptors and bladder contraction found by Tobin et. al. and Lai et. al.

iii. The cited Hashimoto reference does not refute the "reasonable expectation" for choosing Goto's compounds for the treatment of dysuria. On the contrary, said reference shows that it is **within the level of one skilled in the art** to select a known AChE inhibitors disclosed by Goto et. al., and use them in the treatment of dysuria because Goto's compounds are **non-carbamate amine** compounds.

d. Applicant's argument appears to divert from the fact that the claimed method used the same compounds disclosed by Goto et. al. which have the same AChE inhibitory activity. If Goto's compounds with the **same AChE inhibitory activity** cannot treat dysuria, then on what basis could the claimed method treat dysuria with compounds same as those disclosed by Goto et. al.?

e. Thus, it is maintained that at the time that the invention was made, it would have been obvious to use Goto's compounds in view of Tobin et. al. and Lai et. al. for improving excretory potency of an urinary bladder as claimed herein.

Claim Rejections – 112/First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Enablement:** Claim 17 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is maintained for the reasons cited in the previous action, and for the following ones:

a. Applicant contended that "safety and efficacy are not to be confused with the requirement of patentability." It is true that safety and efficacy are not factors for determining enablement. However, safety and efficacy are **critical factors** that contribute to the **unpredictability** of the pharmaceutical art. Combining agents is not a simple task. It requires the skilled clinician to take additional steps to determine not only synergistic effect but also adverse effects as well as toxicity. Thus, undue experimentation would be inevitable.

b. Applicant asserted that the method recited in claim 17 is safe and effective by citing the synergistic effect shown in Tables 8-9 in the specification. However, such a showing does not adequately guide the skilled clinician in selecting a specific combination of the claimed compound with an α-blocker.

In view of the enablement provided by the specification, and the art, it is maintained that the skilled clinician would have to engage in undue experimentation to practice the method recited in the instant claim 17.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tamthom N. Truong
Examiner
Art Unit 1624

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12-23-05

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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